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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/431,607	11/01/1999	LOUIS E. HENDERSON	15280-169300	8955

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EXAMINER	
FOLEY, SHANON A	12

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/431,607	HENDERSON ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

In paper no. 11, applicant amended claim 24. Claims 24-29 are under consideration.

Request for Continued Examination

The request filed on 1/7/3 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/431,607 is acceptable and a RCE has been established. An action on the RCE follows.

Specification

The amendment filed 1/7/3 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: applicant has amended the first line of the specification to include reference to prior application numbers 08/379,420 and "09/312,331". It is noted that the application in quotation marks should be 08/312,331. Although the instant application receives benefit of priority date to 08/379,420 and 08/312,331, the contents of the prior applications "incorporated herein by reference for all purposes" constitutes new matter because the incorporation of these documents was not present at the time the instant application was filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

Claim 25 is objected to because of the following informalities: "Disulfideformamidine" is presumably two words. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

Applicant cites case law and argues that all patent law requires is that the claims be sufficiently clear so that the skilled artisan would be able to determine which compounds are within the scope of the claims. Applicant specifically argues that the skilled artisan would readily recognize that "derivatives containing an NO group" refers to any compound which has NO as a substituent. Applicant has also provided a copy of a definition of "derivative" and emphasizes that they are substances that contain essential elements of the parent substance. In response to the discrepancy noted in the Office action between including NO derivatives while excluding R-C-NO, applicant asserts that the skilled artisan would recognize that the exclusion only applies to compounds where the NO is attached directly to a carbon atom. Applicant states that the addition of a negative limitation to the claims complies with the requirements under the statute.

Applicant's arguments have been carefully considered, but are found unpersuasive. The examiner agrees with the conclusions set forth in the case law cited. However, the metes and bounds of "derivatives containing the NO group" cannot be determined. The definition provided by applicant is insufficient to overcome the rejection because it provides no clear explanation of what the "essential element" of the parent compound is. An "essential element" of a derivative

could be a structural or functional characteristic that is retained from the parent compound. There is no definition of what would be considered "derivatives containing the NO group" in the disclosure. Therefore, it is maintained that "derivatives containing the NO group" have not been described with sufficient clarity to obviate this rejection to satisfy the requirements under the statute. Applicant states that a derivative is any compound containing NO. However, applicant also intends to exclude a broad class of compounds, R-C-NO (which contain NO) from this un-defined group of NO derivatives. The metes and bounds of which compounds are actually excluded from the claims are indeterminable. The exclusionary proviso of R-C-NO from the "derivatives containing the NO group" is indefinite because it cannot be determined what an NO derivative is. Therefore, it is not apparent whether R-C-NO compounds represent a narrower range within the genus of NO derivatives or not.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection maintained for reasons of record.

Applicant argues that the nitroso compounds are distinguished from the NO derivatives because they are listed separately in the specification on pages 19 and 26.

Applicant's arguments, as well as a careful review of the teachings in the disclosure, have been carefully considered but are found unpersuasive. The specific compound listed on page 19, line 11 is R-NO. The compounds intended to be excluded are represented by the formula R-C-NO. Both sets of compounds contain an NO group. Since the NO group is the only feature of the derivative recited for NO derivatives in claim 24 and both R-NO and R-C-NO contain NO, these compounds are indistinguishable from "derivatives containing the NO group".

Applicant cites pages 4 and 5 and states that various nitroso C-nitroso compounds are excluded from the instant method of inactivating a retrovirus. Applicant also asserts that exclusion of the C-nitroso compounds is implicit in the specification because the specification discloses them and the claims exclude them.

A careful review of the passages discussed by applicant has been considered. However, since these nitroso agents are considered derivatives of NO, these compounds are not excluded from the passages cited. Also, as pointed out by applicant, page 19, line 11 specifically lists C-nitroso compounds that dissociate a zinc ion from a retroviral zinc finger. It is also noted that example 2 starting on page 26 is drawn to "C-nitroso redox reactions with CCHC zinc fingers". There is no explicit or implicit teaching in the disclosure that conveys the concept of excluding any compound from the instant claims. The courts have found that any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The prohibitive or exclusionary use of R-C-NO compounds is not conveyed by the original disclosure. Therefore, it is determined that the

specification does not convey that the inventors had basis for the negative limitation in the invention at the time of filing and the added phrase constitutes new matter.

Claims 24-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection maintained for reasons of record.

Applicant summarizes the invention, drawn to a retrovirus that has been inactivated by several classes of compounds. Applicant asserts that each of the compounds have been identified by a functional group that inactivate retroviruses and therefore have been adequately described.

Applicant's arguments have been carefully considered, but are found unpersuasive.

The claims are drawn to an inactivated retrovirus that has been inactivated by "derivatives containing the NO group". As discussed above, the metes and bounds for what would be considered a "derivative" cannot be determined.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is for the derivatives is the presence of an "NO group". There is no identification of any particular portion of a parent compound that must be conserved. Accordingly, in the absence of

sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemi chemical structure of the encompassed genus of "derivatives", and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only specific compounds defined by a definite structure containing an NO group, such as R-NO or R-C-NO, but not the breadth of "derivatives containing the NO group" meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24, 28 and 29 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rice et al. (Nature. Feb., 1993, 361: 473-475) for reasons of record.

Applicant requests that a copy of Dr. Rice's declaration submitted on April 2, 2002 be made of record in the instant case. However, the examiner is regrettably unable to comply with applicant's request because no record of Dr. Rice's declaration can be located. If applicant desires the declaration to be considered, applicant is requested to resubmit the declaration. Any inconvenience this may cause applicant is regretted.

With respect to the rejection of record, applicant states that the mechanism of viral inactivation is recited in amended claim 24.

Applicant's amendment to the claim has been considered. However, this amendment does not obviate the rejection of record. Rice et al. inactivate HIV with C-nitroso compounds. As discussed above, exclusion of these compounds from the claims represents new matter. These compounds are also considered "derivatives containing the NO group". Therefore, the teachings of Rice et al. clearly anticipate the instant claims.

Claim Rejections - 35 USC § 102

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 24-26, 28 and 29 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ryser et al. (PNAS. May 1994. 91: 4559-4563) for reasons of record.

Applicant argues that Ryser et al. do not anticipate the instant invention because Ryser et al. do not teach inhibition of HIV zinc fingers. Applicant states that the removal of the zinc ion from the retrovirus renders the instant retrovirus different from retroviruses that have been inactivated differently.

Applicant's arguments, as well as a careful review of the reference have been considered, but are found unpersuasive. The claims require an inactivated retrovirus that has been inactivated by a disulfide having the formula R-S-S-R. Ryser et al. anticipate an inactivated retrovirus that has been inactivated with 5, 5'-dithiobis(2-nitrobenzoic acid). This compound is listed in instant claim 25 and is known in the prior art. Since the compound is a disulfide and inactivates HIV, the teachings of Ryser et al. anticipate each element in the claims. "The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 and § 2141.02. Applicant's inactivated

retrovirus, described in product-by process terms, reasonably appears to encompass disrupted zinc fingers that are indistinguishable from the reference's inactivated retrovirus. Therefore, even though Ryser et al. do not explicitly teach zinc finger disruption, this would be an inherent property of the compound of Ryser et al. The invention as claimed is seen as prima facie obvious, if not anticipated by the reference.

Claims 24-29 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Williams et al. (WO 94/193321) for reasons of record.

Applicant argues that Williams et al. do not teach any of the instant compounds disclosed or an inactivated retrovirus with disrupted zinc fingers.

In response, the Office provided applicant with an HCAPLUS search result showing that the instant Aldrithiol-2 of claim 27 has an identical CAS registry number to the Bis (4-chlorophenyl) disulfide of Williams et al. in paper no. 5, mailed 10/2/01. Williams et al. claims inactivating HIV reverse transcriptase and infection in claims 14 and 15 with the compounds of claim 1. Although Williams et al. do not specifically teach disrupting zinc fingers with the compound, this characteristic would be an inherent feature of the product for the same reasons presented in the discussion of Ryser et al. Therefore, the inactivated HIV of Williams et al. anticipates or renders the instant invention prima facie obvious.

Claims 24-26, 28 and 29 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Levine et al. WO 93/15730 for reasons of record.

Applicant argues that viruses that are inactivated differently from the claimed disruption of zinc fingers are distinct from those instantly claimed. Applicant concludes that since Levine et al. do not disclose disruption if zinc fingers, the virus of Levine et al. is not anticipated.

Applicant's arguments have been carefully considered, but are unpersuasive. Levine et al. teach that 5,5'-dithiobis(2-**nitro**benzoic acid), a derivative of NO and specifically recited in instant claim 25, inactivates retroviruses. Therefore, the method of Levine et al. comprising the compound and the HIV with a disabled viral protease anticipates a composition comprising an inactivated retrovirus since the compound inhibits the virus replication. Disruption of the zinc fingers by the compound of Levine et al. is an inherent property of 5,5'-dithiobis(2-nitrobenzoic acid). Therefore, the inactivated HIV of Levine et al. anticipates or renders the instant invention prima facie obvious.

Claims 24, 28 and 29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Levine et al. (WO 92/15329) for reasons of record.

Applicant argues that viruses that are inactivated differently from the claimed disruption of zinc fingers are distinct from those instantly claimed. Applicant concludes that since Levine et al. do not disclose disruption if zinc fingers, the virus of Levine et al. is not anticipated.

Applicant's arguments as well as a careful review of the reference have been carefully considered, but are found unpersuasive. Levine et al. anticipates an inactivated retrovirus that has been inactivated with a copper ion delivery agent. Although Levine et al. do not specifically teach disrupting zinc fingers with the compound, this characteristic would be an inherent feature

of the product for the same reasons presented in the discussion of Ryser et al. Therefore, the inactivated HIV of Levine et al. anticipates or renders the instant invention prima facie obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6-9 and 25-28 of U.S. Patent No. 6,001,555. Although the conflicting claims are not identical, they are not patentably distinct from each other because when the method of disrupting a CCHC zinc finger of a retroviral nucleocapsid protein claimed in '555 is applied to a whole retrovirus, the resulting product would be the composition instantly claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
March 18, 2003

James C. Housel
3/24/03

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